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Strategic Management of Valve Infolding in Evolut TAVR Procedures: Enhancing Outcomes and Ensuring Patient Safety

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ABSTRACT

Transcatheter aortic valve repair (TAVR) presents a minimally invasive alternative to traditional surgical valve replacement, albeit not without its own set of complications. A rare complication is the infolding of the self-expanding valve, which can precipitate cardiac arrest. The estimated incidence rate of this complication stands at 1.6%. The management of this complication hinges on either balloon dilation or valve replacement. This article discusses a case involving a 78-year-old man with symptomatic severe aortic valve stenosis. Following TAVR, the patient experienced asystole due to valve infolding, highlighting the need for heightened vigilance and refined intervention strategies in the management of TAVR complications.

Aortic stenosis (AS) is the most prevalent valvular disorder, caused by calcification, congenital valve anomalies, and rheumatic heart disease.[1–3] Diagnosis relies on clinical presentation and echocardiography with severity ranging from at-risk to symptomatic severe AS.[4] While early stages are managed medically, advanced cases necessitate transcatheter aortic valve repair (TAVR), surgical aortic valve repair, or balloon valvuloplasty, which is primarily palliative but can serve as bridge in select cases.[5]

Evolving TAVR options, including balloon-expanding and self-expanding aortic valves, offer less invasive alternatives to surgery. Innovations across generations of self-expanding supra-annular systems, such as the CoreValve, Evolut R, and Evolut PRO (all Medtronic), which have notable reductions in complications like aortic regurgitation.[6] Nonetheless, the TAVR procedure is not devoid of risks, encompassing a spectrum of vascular and cardiac complications that necessitate meticulous management strategies.[7]

Factors that can contribute including puncture site, sheath size, and puncture type.[7] A rare complication is infolding of the valve with failure of expansion of the self-expanding valve. A recent study identified 34 cases in a 6-year span, with most cases occurring with the Evolut R.[8] Other studies estimate an incidence of 1.6%.[9] Predisposing factors include heavily calcified native valves, resheathing of second-generation valves and lack of predilation.[8]

We describe a rare case of hemodynamic compromise due to infolding and failure of expansion of a self-expanding valve, which was promptly managed by balloon expansion of the valve and temporary mechanical circulatory support with Impella (Abiomed) and extracorporeal membrane oxygenation (ECMO) with final recovery of the patient.

Clinical presentation and diagnostic findings

A 78-year-old Hispanic man with a notable medical history of atrial fibrillation, severe tricuspid regurgitation, and peripheral artery disease was evaluated for exertional dyspnea. The patient reported no chest discomfort, palpitations, or other cardiac-related symptoms. Diagnostic imaging, including transthoracic and transesophageal echocardiography, revealed severe AS, with measurements indicating a mean aortic

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valve gradient of 41.8 mm Hg, peak aortic velocity of 4.1 m/s, and an aortic valve area of 0.59 cm^2. Computed tomography angiography for TAVR showed annulus area of 430 mm^2 and perimeter of 75 mm. Hemodynamic assessment through right and left heart catheterization and coronary angiography identified elevated filling pressures in the absence of significant coronary artery disease. The consensus of the heart team, considering the patient's clinical profile and diagnostic outcomes, was to proceed with a transfemoral approach for TAVR.

Interventional procedure and immediate management

The interventional procedure was conducted in the catheterization laboratory, where access was established via the right femoral artery. A 34-mm Evolut PRO+ valve was advanced through the delivery sheath. Initial imaging revealed minimal infolding within the acceptable range, as delineated in the implantation guidelines (Figure 1). However, the onset of asystole during valve deployment necessitated immediate cardiopulmonary resuscitation. Despite the decision to fully deploy the valve, the patient remained hemodynamically unstable, prompting the insertion of ECMO via the left femoral artery for circulatory support. Subsequent imaging, on both cine angiogram and transesophageal echocardiogram, confirmed significant valve infolding and incomplete expansion (Figure 2). Intervention with 26 mm and 30 mm balloon postdilations resulted in successful valve expansion (Figure 3). The subsequent assessment showed stabilized valve hemodynamics and functional aortic valve performance. Given the elevated left ventricular end-diastolic pressure, an Impella CP device was used for left ventricular decompression through the right femoral artery, following the removal of the TAVR delivery sheath.

Postinterventional course and outcomes

The patient's postprocedural course involved gradual weaning from Impella and ECMO support, leading to their removal. The patient was subsequently transitioned to a rehabilitation facility. A 30-day follow-up echocardiogram confirmed optimal aortic valve function, characterized by a mean gradient of 8 mm Hg, absence of significant paravalvular regurgitation, and maintained left ventricular function. Clinically, the patient showed remarkable improvement with resolution of symptomatic dyspnea.

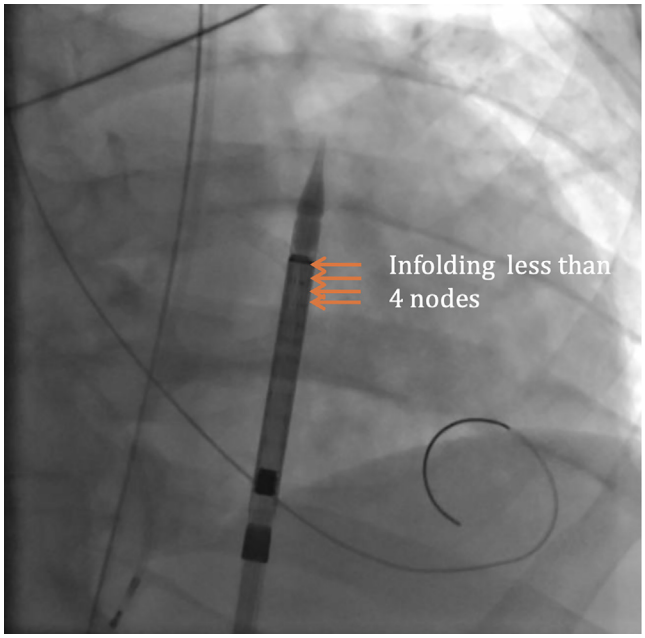

Figure 1.
Minimal infolding within range was visualized in the prevalve deployment fluoroscopy.

Figure 2.
After deployment, the Evolut PRO+ valve appeared to have significant infolding and incomplete expansion on fluoroscopy, causing asystole and mandating extracorporeal membrane oxygenation insertion.

Discussion

Infolding in the Evolut valve series, although rare, is a significant challenge in TAVR procedures. Its incidence may vary with device generations. This case involved an Evolut PRO+ valve, part of Medtronic's current self-expanding series. Infolding is more likely in scenarios with heavily calcified native valves, device misloading, and insufficient predilation. Larger 29-mm and 34-mm Evolut models may be particularly prone to infolding when deployed in smaller anatomical confines.

This case underscores the following key points in TAVR management:

1. Predeployment screening: Careful valve inspection under fluoroscopy while in the inline sheath is to ensure proper loading and identify potential issues before valve introduction.
2. Sizing considerations: Proper annulus sizing and consideration of predilation in challenging anatomies may prevent infolding.
3. Prompt recognition and management: Quick identifying and addressing valve infolding, including balloon postdilation, is essential.
4. Mechanical support: For severe hemodynamic compromise, mechanical circulatory support devices like Impella and ECMO can be life-saving.

Recent literature suggests an incidence rate of approximately 1.6% underscoring the rarity yet clinical relevance of this complication.[9] In particular, prone to infolding are the larger 29.0- and 34.0-mm Evolut valve models when deployed within comparatively smaller anatomical confines. This complication not only emphasizes the critical importance of meticulous predeployment imaging—specifically, cine angiography to ascertain the presence of infolding of fewer than 4 nodes—but also

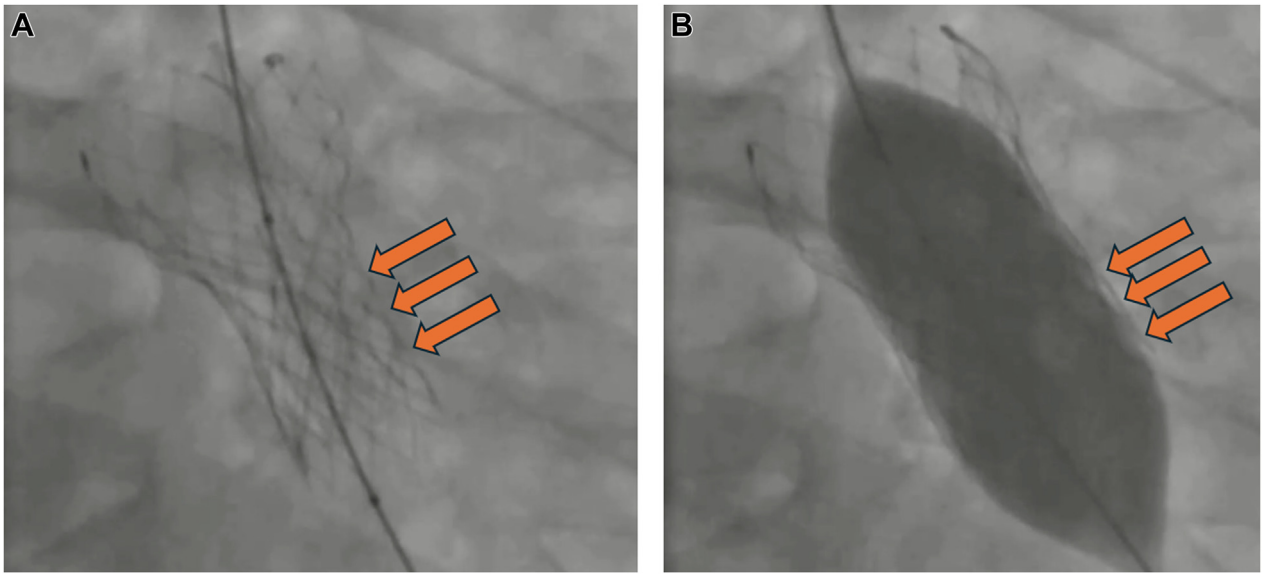

Figure 3.
(A) Valve with significant infolding and underexposing of cells. (B) Fully expanded valve postdilation with 30-mm balloon and resolution of infolding.

highlights the potential for severe clinical outcomes, including hemodynamic collapse, cerebrovascular events, paravalvular leakage, and arrhythmias.

The immediate and effective management of valve infolding demands a comprehensive approach that extends beyond simple mechanical correction of the valve's position. The utilization of balloon dilation to rectify valve infolding represents the first line of intervention. However, the role of adjunctive hemodynamic support mechanisms, notably Impella devices and ECMO, cannot be overstated. These technologies are instrumental in stabilizing the patient, not just ensuring survival but also optimizing the overall outcome of the procedure. This case exemplifies the critical nature of recognizing and swiftly addressing the complication of valve infolding, incorporating advanced supportive therapies to mitigate the risk of potentially life-threatening sequelae.

Conclusions

Valve infolding associated with the Evolut TAVR platform, while rare, poses a significant challenge that requires prompt, effective intervention. This case underscores the importance of balloon dilation for immediate correction, complemented by mechanical circulatory support devices such as Impella and ECMO, to ensure patient stability and optimize outcomes.

Declaration of competing interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Ethics statement and patient consent

Written informed consent was obtained. This study was carried out in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki).

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